Attorney Docket No.:50124/01101

REMARKS

Claims 1 - 35 and 47 - 52 remain pending in the present application. Claims 53 - 55 have been withdrawn from consideration. Claim 21 has been amended. No new matter has been added. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 1 - 4, 6, 9, 10, 12-18, 20, 21, 23, 24, 27, 28, 30 and 32 - 34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,551,301 to Gijsbers et al. ("Gijsbers") in view of U.S. Patent Publication No. 2004/0116789 to Cancro et al. ("Cancro") in further view of U.S. Patent No. 6,575,928 to Saul et al. ("Saul").

Claim 1 recites a method of treating a central nervous system (CNS) disorder, comprising the steps of "*inserting into a patient's body first and second conduits so that distal ends of the first and second conduits open to a portion of the patient's CNS with direct access to cerebrospinal fluid (CSF) and so that a proximal end of the first conduit opens into a first reservoir of material to be introduced into the CSF and a proximal end of the second conduit opens to drain CSF withdrawn from the CNS* and *permanently prevent the withdrawn CSF from reentering the CNS*; detecting and analyzing brain activity of a patient; determining a chemical imbalance present in the CSF by one of a microassay of a sample of CSF and the detected and analyzed brain activity; and treating the patient based on the determined chemical imbalance by one of supplying an agent to the CSF via the first conduit and withdrawing a quantity of CSF via the second conduit."

Gijsbers, on the other hand, purports to disclose a device recirculating previously withdrawn CSF to the patient. As shown in Figure 1, CSF is withdrawn via conduit 12, treated in ion concentration adjustment mechanism 16, and then reintroduced to the patient via conduit 18. Thus, Gijsbers does not teach a method of " *inserting into a patient's body first and second*

conduits so that distal ends of the first and second conduits open to a portion of the patient's CNS with direct access to cerebrospinal fluid (CSF) and so that a proximal end of the first conduit opens into a first reservoir of material to be introduced into the CSF and a proximal end of the second conduit opens to drain CSF withdrawn from the CNS and *permanently prevent the withdrawn CSF from reentering the CNS*", as recited in claim 1.

Specifically, Gijsbers includes conduits 12 and 18 connected to one another via a pump 14 and an ion concentration adjustment mechanism 16. Altering the Gijsbers device to "*permanently prevent the withdrawn CSF from reentering the CNS*" would be detrimental to the Gijsbers device, as this recirculation of the CSF is vital to the performance of the modification of the ion concentration of the CSF which is the main function of the Gijsbers device. Indeed, the key feature of the Gijsbers device is to "change[] the ion concentration in brain fluid" by removing the fluid from the body, adjusting the ion concentration and re-injecting it into the brain. (*Gijsbers*, col. 2, ll. 53-56). It is respectfully submitted that the change proposed by the Examiner fundamentally alters the Gijsbers device by preventing this re-injection of treated CSF, defeating the adjustment of the ion balance which is critical to the epilepsy-treatment to which the device is directed. It is therefore respectfully submitted that those skilled in the art would not be motivated to eliminate this recirculation of the CSF and that such a modification is, in fact, taught away from by Gijsbers.

Cancro relates to a method of 3-D brain source localization that does not involve any withdrawal of CSF. It is therefore noted that Cancro does not overcome the above-noted deficiency in Gijsbers.

Saul is directed to a device and method for the control of CSF flow draining from the body. Specifically, Saul discloses a method by which a flow detection component 80 and flow control component 60 are attached to an access component 50 to remove CSF from the body. (*See* Saul, col. 7, ll. 23-32). However, Saul fails to teach or suggest "inserting first and second

conduits so that distal ends of the first and second conduits open to a portion of the patient's CNS with direct access to cerebrospinal fluid (CSF) and so that a proximal end of the first conduit opens into a first reservoir of material to be introduced into the CSF *and a proximal end of the second conduit opens to drain CSF withdrawn from the CNS and permanently prevent the withdrawn CSF from reentering the CNS*", as recited in claim 1. Rather, Saul discloses the use of a single access component to remove CSF. (*See* Saul, col. 7, ll. 23-25). No additional conduit is disclosed for "supplying an agent to the CSF," as recited in claim 1.

It is therefore respectfully submitted that neither Gijsbers, Cancro nor Saul, either alone or in combination teach a device with *first and second conduits* having distal ends "open to a portion of the patient's CNS with direct access to cerebrospinal fluid (CSF)" wherein "a proximal end of the first conduit opens into a first reservoir of material to be introduced into the CSF and *a proximal end of the second conduit opens to drain CSF withdrawn from the CNS and permanently prevent the withdrawn CSF from reentering the CNS*", as recited in claim 1. Furthermore, it is noted that the combination suggested by the Examiner is taught away from by Gijsbers as it would frustrate the purpose of this device. Furthermore, it is respectfully submitted that the only fluid supplied to the CSF by any of the cited references is the ion concentration adjusted CSF of the Gijsbers device. Thus, it is respectfully submitted that none of the cited references either shows or suggests a conduit for "supplying an agent to the CSF," as recited in claim 1.

For these reasons it is submitted that claim 1 is allowable. Because claims 2 - 4, 6, 9, 10 and 12 - 18 depend from and therefore include all the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Similarly to claim 1, claim 20 recites a system for treating disorders of the central nervous system (CNS), comprising "first and second conduits, wherein, when in an operative position, distal ends of the first and second conduits open into a portion of a patient's CNS with direct

access to cerebrospinal fluid (CSF) and wherein, when in the operative position, a proximal end of the second conduit opens to drain CSF from the CNS and permanently prevent the drained CSF from reentering the CNS," and "a first pump coupled to the reservoir and the first conduit for introducing the first material to the CNS via the first conduit." Thus, it is respectfully submitted that claim 20 and the dependent claims 21, 23, 24, 27, 28, 30 and 32 - 34 are allowable for the same reasons stated above in regard to claim 1.

In addition, Applicant notes that neither Gijsbers nor Cancro nor Saul teach "a first reservoir implantable within the patient's body..." for holding a material to be introduced into the CSF, as recited in claim 20. Cancro does not relate in any way to withdrawing CSF or treating it with therapeutic agents maintained in reservoirs and so shall not be discussed further. Saul does not address the matter of introducing agents into the CSF but rather, is directed solely to the drainage of CSF from the body. Although the ion concentration adjustment mechanism 16 in Gijsbers treats the ion concentration of withdrawn CSF via "chemical treatment" (column 2, line 52), the chemical used for this treatment is not kept in any reservoir that is implantable inside a body. Since the chemical used by the Gijsbers system to treat CSF is stored outside of the body, Gijsbers does not teach the "first reservoir" of claim 20. Nor is any such implantable reservoir suggested by Gijsbers.

It is therefore submitted that claim 20 is allowable over Gijsbers in view of Cancro in further view of Saul for the additional reason noted above. Because claims 21, 23, 24, 27, 28, 30 and 32 - 34 depend from, and therefore include all the limitations of claim 20, it is respectfully submitted that these claims are also allowable.

Claims 5, 11, 22 and 29 stand rejected under 35 U.S.C. § 103(a) as obvious over Gijsbers in view of Cancro in view of Saul and in further view of U.S. Patent No. 6,436,091 to Harper et al. ("Harper"). It is respectfully submitted that Harper does not cure the deficiencies noted above with respect to Gijsbers, Cancro and Saul and, Applicant respectfully submits therefore that

claims 5, 11, 22 and 29 are allowable for at least the reasons given above in support of the patentability of claims 1 and 20.

Claims 7, 8, 25 and 26 stand rejected under 35 U.S.C. § 103(a) as obvious over Gijsbers in view of Cancro in view of Saul and in further view of U.S. Patent Publication No. 2003/0130645 to Brengle et al. ("Brengle"). It is respectfully submitted that Brengle does not cure the deficiencies noted above with respect to Gijsbers, Cancro and Saul and Applicant respectfully submits that claims 7, 8, 25 and 26 are allowable for at least the reasons given above in support of the patentability of claims 1 and 20.

Claims 19 and 35 stand rejected under 35 U.S.C. § 103(a) as obvious over Gijsbers in view of Cancro in further view of Saul. It is respectfully submitted that Saul as applied to this rejection also does not cure the deficiencies noted above with respect to Gijsbers, Cancro and Saul and Applicant respectfully submits that claims 19 and 35 are allowable for at least the reasons given above in support of the patentability of claims 1 and 20.

Furthermore, claims 19 and 35 recite a method for treating an imbalance "wherein the imbalance is an improper intercranial pressure." Saul, on the other hand, notes that the "[d]evices and methods of the present invention are intended for treating conditions in patients having "normal" intercranial pressures" and the "devices and methods of the present invention are not intended for the treatment of patients having elevated intercranial pressures." (*See* Saul, col. 3, ll. 52 - 64). In contrast, Saul teaches treating only conditions "caused by or otherwise related to the retention and accumulation of toxic substances in the CSF." (*See* Saul, col. 3, ll. 36 - 37). It is therefore respectfully submitted that Saul does not cure the deficiencies of Gijsbers and Cancro and Saul noted above and that claims 19 and 35 are allowable for this additional reason.

Claims 47, 48, 50 and 51 stand rejected under 35 U.S.C. § 103(a) as obvious over

Gijsbers in view of Cancro in view of Saul and in further view of U.S. Patent No. 5,617,873 to Yost et al. ("Yost"). It is respectfully submitted that Yost does not cure the deficiencies noted above with respect to Gijsbers, Cancro and Saul and Applicant respectfully submits that claims 47, 48, 50 and 51 are allowable for at least the reasons given above in support of the patentability of claims 1 and 20.

Furthermore, it is submitted that Yost fails to teach or suggest "initiating a treatment of the patient if the determined intercranial pressure exceeds the predetermined threshold" as recited in claim 48. Yost merely discloses a means for measuring intercranial pressures and calculating absolute values of pressure and volume therefrom. (*See* Yost, col. 2, ll. 19-22). Yost fails to teach or suggest a method in which treatment is initiated when "the determined intercranial pressure exceeds the predetermined threshold," as recited in claim 48. Gijsbers, Cancro and Saul also fail to teach or suggest this limitation. It is therefore submitted that claim 48 is allowable for this additional reason. Claim 51 recites limitations substantially similar to claim 48. It is therefore submitted that claim 51 is allowable for the same reasons as given above with respect to claim 48.

Claim 52 stands rejected under 35 U.S.C. § 103(a) as obvious over Gijsbers in view of Cancro in view of Saul and in further view of U.S. Patent Publication No. 2003/0171711 to Rohr et al. ("Rohr"). It is respectfully submitted that Rohr does not cure the deficiencies noted above with respect to Gijsbers, Cancro and Saul and Applicant respectfully submits that claim 52 is allowable for at least the reasons given above in support of the patentability of claim 20.

Furthermore, it is noted that neither Gijsbers nor Cancro nor Saul nor Rohr teach or suggest "a memory for storing data representing normative brain activity, wherein the brain activity detection unit compares the brain activity to the data representing normative brain activity," as recited in claim 52. Rather, Rohr discloses a control unit comprising a processor and memory where "the processor compiles a database of sensed data and response data for modeling

treatment." (*Rohr*, col. 7, ll. 7 - 10). It is noted that the memory of the control unit of the Rohr device is directed to compiling a database of recorded data and not of "normative brain activity", as recited in claim 52. It is therefore submitted that claim 52 is allowable for at least this additional reason.

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CONCLUSION

In light of the foregoing, Applicant respectfully submits that all of the presently pending claims are in condition for allowance. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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By: _____
Patrick J. Fay (Reg. No. 35,508)

Fay Kaplun & Marcin, LLP
150 Broadway, Suite 702
New York, New York 10038
Tel: (212) 212-619-6000
Fax: (212) 619-0276